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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,703	10/17/2002	Roger Abraham Bunce	(225/40185) Case 37497	2746

7590 10/03/2005

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EXAMINER
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ALEXANDER, LYLE

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 10/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/089,703	BUNCE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Lyle A. Alexander	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                    |                                                                             |
|----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. ____                                                 |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4/1/02</u> .                                                              | 6) <input type="checkbox"/> Other: ____                                     |

*le*

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7-20 and 23-24 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 96/24060, EP 0596867 or Yang et al. (USP 5354692).

WO 96/24060 teach in the last paragraph on page 7 through page 9 slow release agents, separate layers, hydrophobicity, semipermeable membranes and porous elements as barriers.

EP 0596867 teach in column 7 a blocking means(16) positioned between a first zone(14) and a fluid zone(15). The second zone(17) contains a solid phase receptor that binds to reagent(16) of the first zone. Figure 1 shows the first and second zones in partial fluid contact.

Yang et al. teach an immunochromatic device for detection of an analyte comprising a housing, a first liquid permeable material, a second liquid permeable material, a third liquid permeable material, a hydrophobic barrier, a wicking sheet and a detecting reagent.

Claims 1-5 and 7-24 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 930317 or Deutsch et al. (USP 4,522,923).

WO 930317 on page 4 teach a bidirectional flow device. Page 7 lines 16+ teach a first segment for receiving a sample, a second region at which analyte capture

Art Unit: 1743

reagents are immobilized, an absorbent reservoir, a supply of liquid reagent and a soluble barrier. Page 11 in the first full paragraph through page 15 teach a reversible flow technique that has been read on the claimed "liquid flows over the analyte capture region at least twice".

Deutsch et al. teach a device comprising at least two water soluble barriers subdividing the container into at least three compartments that including reagents along a sequential flow path.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

Art Unit: 1743

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/24060, EP 0596867, WO 930317, Yang et al. or Deutsch et al. in view of Skjak-Braek et al. (USP 5,459,054) .

See over WO 96/24060, EP 0596867, WO 930317, Yang et al. and Deutsch et al. supra.

These references are silent to the specifically claimed release means, such as the claimed glucopyranoside (OBDG hereafter).

Skjak-Braek et al. teach in column 7 example the use of OBDG with a semipermeable membrane as a dialyzable surfactant that will change its surface properties based upon the amount of dialysis. OBDG is advantageous in a test device because it can alter the permeability based upon the amount of fluid flowing through the device (e.g. dialyzing).

It would have been within the skill of the art to modify WO 96/24060, EP 0596867, WO 930317, Yang et al. or Deutsch et al. in view of Skjak-Braek et al. and use OBDG to gain the above advantages.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

Art Unit: 1743

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lyle A Alexander  
Primary Examiner  
Art Unit 1743

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